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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,102	03/02/2004	Phillip B. Dolliver	HM-04-PT-02-NP	2431

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HAEMONETICS CORPORATION  
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BRAINTREE, MA 02184-9114

EXAMINER
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REICHLER, KARIN M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/791,102	<b>Applicant(s)</b> DOLLIVER ET AL.	
	<b>Examiner</b> Karin M. Reichle	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Specification***

#### ***Drawings***

1. The drawings are objected to because Figures 3A-3B are not consistent with the descriptions thereof, i.e. the Figures show sectional views but are not described as such. The line from 30 in Figure 1 should be dashed to denote underlying structure. This also applies to Figure 2.

2. In Figure 3A, what is the numeral to the far left of 16? Where are 102, 112 and 149 as described in the last paragraph on page 9 shown? Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Description*

2. The disclosure is objected to because of the following informalities: On page 2, line 15, "of" should be --if--. The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims should be commensurate, see MPEP 608.01(d). As already discussed supra, the descriptions of Figures 3A-B are not consistent with the Figures thereof. On page 7, line 14, "auto transfusion" should be --autotransfusion--. On page 7, line 26, "FIG.3" should be --FIG. 3A--. On page 10, line 12, "FIGS.4A" should be --FIGS. 4A--. Similar corrections should be made to similar language at page 10, line 1, page 11, line 3, page 11, line 100. Also page 10, line 20 appears to be missing a line or lines.

Appropriate correction is required.

### *Claim Objections*

3. Claims 1-11 are objected to because of the following informalities: in line 1 of claims 2-5, 7, 9 and 11, "A" should be --The--. In claim 2, last line, "drain tube" should be --tubing--. In claim 5, line 2, "open to a" should be --in fluid communication with the--. In claim 7, line 3, claim 8, last line, and claim 10, line 7, after "patient", --end-- should be inserted. In claim 8, second to last line, "--" should be deleted. On the third to last line, "and;" should be --; and--. This last objection also applies to similar language in claims 1, 6 and 10. In claim 9, "device" on line 3 should be --system--. In claim 10, lines 8 and 9, "a" should be --the--. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, and 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al '896.

Claims 1, 2 and 5: See Wilson et al at claim 1, Figures, col. 3, lines 32-36, col. 5, lines 17-55, col. 6, lines 45-55 and col. 7, lines 3-16, i.e. tubing is at least 10 or 10, 2 and 3, catheter is 1, collection device is 4 and 5, the vacuum relief valve is adjacent 52 or 152 and open to atmospheric pressure through 28 or 128 and 129.

With regard to lines 1, 3 and 4 of claim 1 which recite function, capability or properties of the claimed structure, i.e. capability of the ends, the tubing and valve, it is the Examiner's first position that Wilson explicitly teaches such at the portions cited supra. In any case, the Examiner's second position, Wilson teaches all the claimed structure as discussed supra. Therefore there is sufficient factual evidence for one to conclude that such function, capability or properties claimed would also be inherent in such same structure, see MPEP 2112.01.

With regard to claims 6-7, see the discussion of claims 1, 2 and 5 and inline anti-reflux valve 42 or 142.

With regard to claim 8, see discussion of claims 1, 2 and 5-7 supra. With regard to claim 8, line 4, see the discussion of the Examiner's second position set forth supra with regard to claim 1.

With regard to claim 9, Applicant claims the function, capability or properties of the ends of the tubing which Wilson does not explicitly set forth. However, compare the diameters of ends 14, 19 and 21 in Figure 1 and see col. 3, lines 18-26, i.e. the ends are not the same size such that they are not interchangeably securable, i.e. end 14 would be too small to secure to the structure 19 and 21 is secured to and end 19 or 20 would be too big to secure to the structure 14 is secured to, and are physically, e.g. visually, distinguishable from one another. Therefore, there is sufficient factual evidence for one to conclude that such function, capability or properties claimed would also be inherent in such distinguishable end structure, see MPEP 2112.01.

6. Claims 1-2 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schalk '980.

Claims 1, 2 and 4-5: See Schalk at the abstract, the Figures, col. 1, lines 16-22, and 44-55, col. 2, lines 29 et seq, col. 3, lines 7-10, col. 4, lines 6-43, i.e. tubing is at least 10, catheter is 12, collection device is 22, 28 and 26, the vacuum relief valve is 76 and opens to atmospheric pressure through orifice 84 and includes a piston 86, and a spring 90.

With regard to lines 1, 3 and 4 of claim 1 which recite function, capability or properties of the claimed structure, i.e. capability of the ends, the tubing and valve, it is the Examiner's first position that Schalk explicitly teaches such at the portions cited supra. In any case, the Examiner's second position, Schalk teaches all the claimed structure as discussed supra. Therefore there is sufficient factual evidence for one to conclude that such function, capability or properties claimed would also be inherent in such same structure, see MPEP 2112.01.

With regard to claims 6-7, see the discussion of claims 1, 2 and 4-5 and inline anti-reflux valve 50.

With regard to claim 8, see discussion of claims 1, 2 and 5-7 supra. With regard to claim 8, line 4, see col. 2, lines 29-49 and the discussion set forth supra with regard to claim 1.

7. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Heimlich '159.

See Heimlich at Figures, col. 1, lines 28-35 and 56-70, col. 3, lines 15-65, col. 4, lines 50-64, i.e. Heimlich teaches a method of controlling flow through a drain tube in a post operative environment comprising providing a drain tube 16 having a lumen therethrough, a patient end joined to a drainage catheter 11, a device end 19 joined to a collection device such as a bag or suction apparatus and an inline anti-reflux valve 22 which permits flow in one direction from the patient to the collecting device. The method of claim 10 is taught by the cited portions of Heimlich.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al or Schalk.

Applicant claims the vacuum relief valve is configured to open when vacuum in the lumen is approximately seventy centimeters of water (5.1 cm Hg or .06 psi) which neither Wilson or Schalk specifically teach. However, on page 12, lines 4-6 of the instant specification it is disclosed only that this level is for procedures in the chest cavity and both Wilson and

Art Unit: 3761

Schalk teach vacuum relief valves configured to open at predetermined levels of vacuum during procedures in the chest cavity to prevent unsafe excess vacuum pressures. Therefore, where, as here, the general conditions of the claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges, i.e. approximately 70 cms of water, by routine experimentation, see *In re Aller*, 105 USPQ 233.

10. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al in view of Heimlich and Seddon et al.

The Wilson et al reference teaches all the steps of claimed methodology, see discussion thereof supra, except for explicitly teaching post-operative environment flow control through a surgical drainage tube. However as set forth in the preamble of claim 1 of Wilson, compare to that of claim 14, Wilson et al contemplates use in a extracorporeal flow circuit for directing or draining a body fluid from the body cavity. Furthermore, as illustrated by Heimlich and Seddon et al, extracorporeal flow circuits for directing body fluids from a body cavity are employed not only in surgical environments but also in postoperative environments as well. Therefore, to employ the method as taught by the Wilson reference not only in surgical environments but post-operative environments as well, if not already, would be obvious to one of ordinary skill in the art in view of the recognition that such multi-environmental use of such circuits is well known such as, for example, illustrated by Heimlich and Seddon et al.




*Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The remainder of the cited but not applied references also show various flow control safeguards in a variety of environments.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Karin M. Reichle  
Primary Examiner  
Art Unit 3761

KMR  
October 25, 2005